## REMARKS

Claims 1-49 are currently pending. Claims 4-30, 32-36, and 44-47 have been withdrawn from consideration. Applicant reserves the right to prosecute the subject matter of the withdrawn claims in one or more continuation, continuation-in-part, or divisional applications.

In the pending, non-final Official Action dated July 12, 2007, claims 37-43 were withdrawn from consideration because the claims were allegedly directed to a non-elected invention. Applicant respectfully disagrees with the withdrawal of these claims. MPEP §806.05(i) states that a restriction requirement can only be made if the process of making a product and the product are distinct. Applicant respectfully asserts that the process of making the instant medical device which is disclosed in claims 37-43 need not be separated by restriction. Claims 37-43 describe a process specially adapted for making the product, *i.e.*, the medical device comprising an amorphous metal alloy. Applicant respectfully submits that all of the pending claims are properly presented in a single application and all claims should continue to be examined together. The Examiner has not shown that examination of all the pending claims would require undue searching and place a serious burden on the Examiner, which is a requisite showing for proper issuance of a restriction requirement. Applicant respectfully submits that claims 37-43 directed to a process of making the product should be examined on the merits together with the other pending claims.

Furthermore, claims 37-43 were amended to method claims because the Examiner previously labeled these claims as product-by-process claims. No new matter

or distinct invention was added to this application by these amendments. Applicant respectfully requests rejoining and reconsideration of claims 37-43.

Claims 31, 37 and 49 have been amended. No new matter is introduced by these amendments and the amendments are supported by the instant specification.

**Response to 35 U.S.C. §103(a) Rejections**

Claims 1-3, 31, 48, and 49 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Shannon, et al. (U.S. 5,928,279) in view of McDonald, et al. (U.S. 5,728,150) or Pinchuk (U.S. 5,019,090) and further in view of Masumoto, et al. (U.S. 4,614,221) or Miyazawa, et al. (U.S. 4,802,776). Applicant respectfully disagrees with this rejection.

The Examiner contends that the device described in Shannon contains all of the elements in claims 1, 31, 37, and 41 except that the metal is amorphous and contains a metalloid. Applicant respectfully disagrees with this assessment of the Shannon reference.

Shannon does not teach or suggest a device that contains an etched amorphous metal alloy. "Etched," as that term is used in the instant specification (p. 12, in example 3, ¶4), includes embodiments that are flat or tubular and may be chemically etched, laser cut, made by EDM or other similar known methods. Etching is known in the stent art to form a pattern of fenestrations in the metal stent structure. The device in Shannon is structurally different from the claimed device. Shannon describes an implantable medical device that is made of "individual components or wires" that are

coated with a PTFE coating. See Shannon, column 6, lines 3-5. Shannon describes a variety of ways to form an implantable device using wires, including helically winding, twisting, or braiding the wires together. Applicant respectfully points out that one skilled in the art would not etch (as that term is used in the instant specification) the metal wires of Shannon to form an implantable device. This would not be practical, and more importantly, would not be necessary because the weaved wires themselves form the stent structure. In fact, the etched devices as claimed are not formed of wires at all, but rather etching is used in forming stents from flat or tubular metal, such as for example, ribbons of metal, be it flat or rolled. Independent claims 1, 31, 37, and 41 all recite an implantable device that is formed by etching an amorphous metal alloy and not by weaving wires, as described in Shannon.

The Examiner has also cited Pinchuk and McDonald for their description of other types of stents. Just like Shannon, neither Pinchuk or McDonald teach or suggest a stent formed of an amorphous metal. The selection of a new material is not a trivial matter. Materials that are deposited in the human body must be tested extensively to determine their suitability for human implantation. Amorphous metals have not been used for devices that are implanted in humans. Therefore, there is no basis for assuming their safety or suitability as the examiner has in the current rejection. Neither Shannon, Pinchuk nor McDonald suggest that an amorphous metal could be used. In contrast, for example, the McDonald reference makes clear in many parts of the specification that "biocompatibility" is important in the material chosen for use in the stent (see McDonald specification at col. 3, lines 52-57; col. 5, lines 7-9; col. 7, lines 7-9 and 31-33; col. 10, lines 42-44; and col. 12, lines 60-62). Without a teaching or

suggestion that amorphous metal is biocompatible, one skilled in the art would not simply exchange a known biocompatible material for a relatively new material that has not yet been tested in the human body. None of the art cited by the Examiner provides this suggestion.

Masumoto describes a method for producing a thin amorphous metal wire. The entire patent is devoted to describing methods for making wires of amorphous metals. Masumoto contains a single reference to uses for the amorphous metal wire, stating: the amorphous metal wire "is superior to conventional metal wire of a crystalline structure in many chemical, electromagnetic, and physical properties" and can be "useful in connection with numerous products such as electric and electronic parts, electromagnetic parts, composite materials and textile materials" (col. 1, 62 – 2, 2), however these properties are not described in any way. One skilled in the art seeking to make an implantable device would have no common sense reason to incorporate the amorphous wires based on the Masumoto reference, because neither Masumoto nor Shannon, McDonald or Pinchuk provide a reason or benefit to making such a device with amorphous metal wires. Moreover, combining the stent references of Shannon, McDonald and/or Pinchuk with Masumoto would not lead to the instant invention as claimed, because the claimed stents are not formed from amorphous metal wires, but rather are etched metals formed into stent structures. For these reasons, the claimed invention is not obvious over the cited references.

Miyazawa is also cited by the Examiner as teaching "forming amorphous sheets of elgiloy". The Miyazawa patent describes a "print head", which is a part of a printer. This area of art has no relation to medical devices. One skilled in the art working in

medical devices would not look to art in the area of printer technology for guidance on how to make a better stent. The reference comes from a completely non-analogous field of technology and the material is not shown to be biocompatible. MPEP 2141.01(a) states that "[i]n order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." (citing *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992)). Printer heads are not at all applicable to applicant's field of endeavor and further are not reasonably pertinent to the particular problem with which the instant invention is concerned: i.e., the Miyazawa printer reference is not pertinent to creating an implantable device that is made of a strong, highly elastic, biocompatible material, i.e. the particular problem with which the inventor was concerned. See page 1 of the instant specification. Therefore, Miyazawa is not an appropriate reference to cite in a rejection of a stent structure because it is non-analogous prior art. As a result, the combination of Shannon, McDonald and/or Pinchuk in view of Masumoto and/or Miyazawa do not render the instant claims obvious pursuant to 35 U.S.C. §103(a). Applicants respectfully request reconsideration and withdrawal of this §103 rejection.

The Examiner has also rejected claims 1-3, 31, 48, and 49 under 35 U.S.C. §103(a) as being unpatentable over Shannon, et al. in view of Masumoto, et al. as applied in the preceding paragraphs and Fariabi (U.S. 5,636,641). Applicant respectfully disagrees with this rejection.

As discussed in detail above, Shannon in view of Masumoto does not teach or suggest an etched amorphous metal stent as claimed. Neither reference, alone or

taken together, would lead the skilled artisan in the field of medical devices to the invention as claimed. Shannon describes wire stents. Masumoto is limited to a description of thin amorphous metal wires. The references in combination contain no teaching or suggestion that amorphous metals are biocompatible or that such metals can be formed into stent structures that can be etched as defined by the instant specification.

The Fariabi reference does not remedy the deficiencies of the Shannon/Masumoto combination. Fariabi describes a process of "etching" wires to remove surface oxides. This "etching" process is distinct from the "chemical etching" or "laser cutting," for example, described in the instant specification as "etching". "Etching" as used in the instant application forms a pattern of fenestrations in the metal itself. It is not a cleaning process as used in Fariabi. One skilled in the medical stent art is aware of the distinction and would understand that the methods of Fariabi would not be used to produce a stent as recited in the instant claims. Furthermore, there is no teaching or suggestion that the etching methods described in Fariabi would be applicable to amorphous metals. Thus, the combination of Shannon and Masumoto, in view of Fariabi does not teach or suggest the instant claims.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) as to claims 1-3, 31, 48, and 49 are respectfully requested for the above reasons and in view of the claim amendments.

## CONCLUSION

Based on the foregoing amendments and remarks, applicant respectfully requests reconsideration and withdrawal of the rejections of the pending claims and requests allowance of this application.

## AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-4387**, Order No. 92110.002.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-4387**, Order No. 92110.002.

Respectfully submitted,
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Dated: November 13, 2007

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